Claim Amendments

This listing of claims will replace all versions, and listings, of claims in the application claims as follows.

Listing of Claims

Claims 1-18. (Canceled)

Claim 19. (New): A process for the preparation of aqueous suspensions for use as pharmaceutical formulations for inhalation by nebulization, which comprises:

in a turboemulsifier apparatus comprised of a circular container having a base with an opening therein which receives a turbine device and which contains an aqueous solution, and a loading hopper, which contains a sterile micronized active ingredient, connected to said turbine by a conduit:

a) operating said turbine containing an aqueous solution and applying a vacuum to the turboemulsifier, thereby drawing the sterile micronized active ingredient by vacuum into the aqueous solution to form a dispersion of the micronized active ingredient; and

b) homogenizing the micronized active ingredient in the suspension.

Claim 20. (New): The process as claimed in claim 19, wherein the homogenized suspension is distributed into containers.

Claim 21. (New): The process as claimed in claim 19, wherein the aqueous solution contains additives or excipients selected from the group consisting of wetting, stabilizing, isotonic and buffering agents.

Claim 22. (New): The process as claimed in claim 19, wherein the micronized active ingredient is a corticosteroid.

Claim 23. (New): The process as claimed in claim 19, wherein the aqueous solution has been sterilized by heat or filtration.

Claim 24. (New): The process as claimed in claim 22, wherein the micronized corticosteroid is sterilized by irradiation or by heat.

Claim 25. (New): The process as claimed in claim 22, wherein the micronized corticosteroid is beclomethasone dipropionate which is sterilized by being subjected to gamma radiation.

Claim 26. (New): The process as claimed in claim 19, wherein the homogenization of the suspension is conducted at a turbine speed ranging from 750 to 4000 rpm for 5 to 60 minutes.

Claim 27. (New): The process as claimed in claim 26, wherein the homogenization conditions are a turbine speed ranging from 1600 to 3000 rpm for 20 to 40 minutes.

Claim 28. (New): The process as claimed in claim 27, wherein homogenization is achieved at a turbine speed of 2900 rpm for 30 minutes.

Claim 29. (New): The process as claimed in claim 19, wherein at least 90 % of the micronized active ingredient have a Feret diameter of less than or equal to 8 μm.

Claim 30. (New): The process as claimed in claim 19, wherein said containers are monodose vials.

Claim 31. (New): The process as claimed in claim 19, wherein the turboemulsifier is provided with an agitation system.

Claim 32. (New): The process as claimed in claim 19, wherein the turbine is provided with a radial nozzle system.

Claim 33. (New): The process as claimed in claim 21, wherein the isotonic agent is sodium chloride.

Claim 34. (New): The process as claimed in claim 21, wherein the wetting agent is selected from the group consisting of polysorbate 20 and sorbitan monolaurate.

Claim 35. A pharmaceutical formulation for administration by nebulization which contains the homogenized aqueous suspension prepared by the process of Claim 19.

Claim 36. (New): The pharmaceutical formulation as claimed in claim 35, wherein the active ingredient is a corticosteroid selected from the group consisting of BDP, mometasone furoate, flunisolide, budesonide, fluticasone propionate and ciclesonide.

Claim 37. (New): The pharmaceutical formulation as claimed in claim 35, wherein the active ingredient is present in the aqueous suspension at a concentration ranging from 0.01 to 0.1 % w/v.

Claim 38. (New): The pharmaceutical formulation as claimed in claim 35, wherein unit dose formulations of the pharmaceutical formulation are pre-formed or produced with the "blow, fill and seal" technology.

Claim 39. (New): A pharmaceutical formulation in the form of an aqueous suspension that is to be administered by nebulization, comprising:

as active ingredient, a micronized sterile corticosteroid, wherein the median volumetric diameter of 90 % of the particles is less than 8 μm and wherein 50 % of the particles range in size from 2 to 3.5 μm as determined by a Malvern apparatus.

Claim 40. (New): The pharmaceutical formulation as claimed in claim 39, wherein the median volumetric diameter of 90 % of the particles is less than 7 μm and wherein 50 % of the particles range in size from 2.5 to 3 μm.

Claim 41. (New): The pharmaceutical formulation as claimed in claim 39, wherein the micronized sterile corticosteroid is beclomethasone dipropionate.

Claim 42. (New): The process as claimed in Claim 41, wherein beclometasone dipropionate is present in the aqueous suspension at a concentration of 0.04 % w/v.

Claim 43. (New): A method of treating lung diseases, comprising:

administering by nebulization the pharmaceutical formulation as claimed in claim 40 by once-a-day administration.

Claim 44. (New): The method as claimed in claim 43, wherein the lung disease is asthma or chronic bronchitis.